Title: Roles and Responsibilities of Principal Investigators and Their Research Teams

The intent of this Standard Operating Procedure (SOP) is to define the roles and responsibilities of Principal Investigators and their research team that utilize live vertebrate animals in research or teaching activities at Illinois State University (ISU). This SOP is intended for use by researchers or anyone who cares for or uses animals at ISU. This SOP is approved by the ISU Institutional Animal Care and Use Committee (IACUC). Any deviation must be approved by the IACUC prior to its implementation.

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1. Serving as a Principal Investigator on an Animal Use Study

The Principal Investigator (PI) is responsible for all aspects of the study including, implementation, research team training and oversight, for the actions of his/her research team, and for ensuring that all policies of the IACUC and the Office of Research Ethics and Compliance (REC) are followed. Only an ISU faculty/staff member may serve as a PI. All correspondence regarding their studies must be directed to or received from the PI.

2. Principal Investigator Responsibilities

PI responsibilities include but are not limited to:

- Reviewing the ISU policies regarding animal care and use;
- Consulting with REC regarding their animal needs, including space and species requirements;
- Developing and submitting an animal use study and ensure that no research is initiated until IACUC approval is obtained;
- Obtaining appropriate wildlife permits for IACUC related activities;
- Responding to the comments of the IACUC;
- Ensuring that all members of the research team are trained in the appropriate and relevant methods, species, and procedures as well as being extremely familiar with the study protocol;
- Conducting the study protocol as approved;
- Establishing data security polices for the lab as appropriate;
- Submitting adverse-event/incident reports as required by the IACUC;
- Maintaining approval for the duration of the study; and
- Submitting any changes to the study protocol for approval and initiating changes only after IACUC approval is received.

Investigators are also responsible for complying with federal, state, or local regulations on animal use and with other ISU and IACUC policies and procedures, such as biosafety, radiation safety, and transportation. Failure to do so may result in suspension or termination of the approved protocol, including notification to the regulatory agencies and PI funding agencies.

3. Granting Agency Requirements and Protocol Submission

Many agencies will not review proposals involving animals unless formal notification of IACUC review and approval has been provided. Other agencies may review and score proposals, but they will withhold funding pending notification of IACUC review and approval is received.

PI's are urged to discuss agency requirements with the Research and Sponsored Programs office (RSP) office to ensure adequate time it allotted for IACUC review. As well as submitting the IACUC protocol prior to the submission of a grant application and should consider the time required when preparing their timeline.
Proposals for funding that involve the use of animals are carefully reviewed prior to receiving institutional endorsement. The review ensures that a protocol is active and the approval date listed is correct, and that PI of the study is listed as either the PI of the study or as a member of the research team. If a proposal is submitted prior to receiving approval for the relevant study protocol, the University will not process the award or provide a University account until the study protocol is fully approved.

Externally funded studies may require a congruency review to ensure that the animal activities described in the grant proposal are covered in the approved IACUC study. The award will not be released until congruency with the approved study has been completed, except in limited circumstances. PIs should consider the time requirements when preparing a grant proposal.

4. Research Team

The research team may be composed of co-investigators, fellows, technicians, staff and students. Each member of the research team may work independently from the PI. Each member of the research team needs to be listed in the protocol and this list updated via amendment as needed.

While the PI is held responsible for all aspects of the conduct of animal use, each member of the research team bears a responsibility to ensure that animals are used in strict accordance with the protocol, institutional policy, and the ethical principles governing animal use. Therefore, each member of a research team must receive appropriate training, must understand the study protocol and must be committed to the humane care and use of animals. The specific training requirements may be found in the Vertebrate Animal Care and Use Training SOP.

Animal care staff are not considered a part of the research team; nor are students handling animals as part of a class where their animal contact is continually monitored. Refer to the SOP entitled, “Vertebrate Animal Care and Use Training” for training requirements for those individuals.

5. Documentation/Records

PI's and their team bear much of the responsibility to prepare and maintain records of the many aspects of animal care and use that are required by regulation and practice. Such records include, for example, records of: animals received, animals used under each protocol, anesthesia, analgesia, post-procedural care, euthanasia method and date, controlled substance use, training, breeding, basic animal care, and clinical care records. Consult REC if you have any questions about the record keeping requirements. Records must be maintained for at least 3 years following closure of the study.